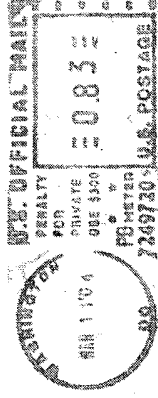


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**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

27

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

**NOTICE OF ALLOWABILITY**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to Re. RCF filed 1/15/04

☒ The allowed claim(s) is/are 10 & 12-14

☐ The drawings filed on 2/5/01 are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☐ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. \_\_\_\_\_

☐ including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 23, 25, & 26

☐ Notice of Draftperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☐ Examiner's Statement of Reasons for Allowance



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## NOTICE OF ALLOWANCE AND FEE(S) DUE

23117 7590 03/11/2004

NIXON & VANDERHYE, PC  
1100 N GLEBE ROAD  
8TH FLOOR  
ARLINGTON, VA 22201-4714

EXAMINER

STUCKER, JEFFREY J

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 03/11/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,805	02/05/2001	Barton F. Haynes	1579-548	4002

TITLE OF INVENTION: HUMAN IMMUNODEFICIENCY VIRUS IMMUNOGENIC COMPOSITION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1330	\$0	\$1330	06/11/2004

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

# PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail**

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**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

23117 7590 03/11/2004

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,805	02/05/2001	Barton F. Haynes	1579-548	4002

TITLE OF INVENTION: HUMAN IMMUNODEFICIENCY VIRUS IMMUNOGENIC COMPOSITION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1330	\$0	\$1330	06/11/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
STUCKER, JEFFREY J	1648	424-192100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

- ☐ Issue Fee
- ☐ Publication Fee
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s):

- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Director for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.** SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,805	02/05/2001	Barton F. Haynes	1579-548	4002
23117	7590	03/11/2004		
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714				
			EXAMINER STUCKER, JEFFREY J	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 03/11/2004

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 58 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 58 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Art Unit: 1648

This Notice of Allowability is in response to the RCE filed 2/5/04. Claims 10 and 12-14 are pending and allowable.

The following is an Examiner's Statement of Reasons for Allowance:

The plethora of prior art supplied by applicant does not appear teach or suggest the claimed peptide.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (703) 872-9306.

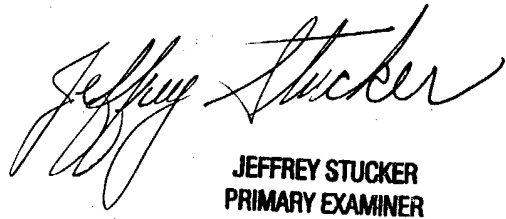
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.



**JEFFREY STUCKER**  
**PRIMARY EXAMINER**

**INFORMATION DISCLOSURE  
CITATION**

(Use several sheets if necessary)

Atty. Docket No.

**1579-548**

Applicant

**HAYNES et al**

Filing Date

**February 5, 2001**

Serial No.

**09/775,805**

Group

**1648**

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>JS</i>	5,030,449	7/1991	Berzofsky et al			
	5,853,978	12/1998	Berman et al			
	5,864,027	1/1999	Berman			
	5,932,218	8/1999	Berzofsky et al			
	5,939,074	8/1999	Berzofsky et al			
	6,042,836	3/2000	Berman et al			
	6,290,963	9/2001	Fischinger et al			
	6,294,322	9/2001	Berzofsky et al			
	6,458,527	10/2002	Luciw et al			
	5,081,226	1/1992	Berzofsky et al			
	5,336,758	8/1994	Berzofsky et al			
	5,622,703	4/1997	Berzofsky et al			
	5,695,762	12/1997	Berzofsky et al			
	5,711,947	1/1998	Berzofsky et al			
	5,820,865	10/1998	Berzofsky et al			
	5,882,853	3/1999	Berzofsky et al			
	5,976,541	11/1999	Berzofsky et al			
	5,980,899	11/1999	Berzofsky et al			
	5,997,869	12/1999	Golez et al			
	6,214,347	4/2001	Berzofsky et al			
	6,592,872	7/2003	Klimpel et al			

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	ENGLISH ABSTRACT YES / NO
<i>JS</i>	WO 93/04697	3/1993	WIPO		
	WO 94/26785	11/1994	WIPO		
	WO 94/28929	12/1994	WIPO		
	WO 94/29339	12/1994	WIPO		
	WO 98/01564	1/1998	WIPO		
	WO 02/08716	1/2002	WIPO		X
	WO 2002/20554	3/2002	WIPO		

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

<i>JS</i>	Ahlers, et al., "Construction of an HIV-1 Peptide Vaccine Containing a Multideterminant Helper Peptide Linked to a V3 Loop Peptide 18 Inducing Strong Neutralizing Antibody Responses in Mice of Multiple MHC Haplotypes After Two Immunizations", The Journal of Immunology, Vol. 150, No. 12, pp. 5647-5665 (1993)
<i>JS</i>	Ahlers, et al., "Candidate HIV Type 1 Multideterminant Cluster Peptide-P18MN Vaccine Constructs Elicit Type 1 Helper T Cells, Cytotoxic T Cells, and Neutralizing Antibody, All Using the Same Adjuvant Immunization", AIDS Research and Human Retroviruses, Vol. 12, Number 4, pp. 259-272 (1996)
<i>JS</i>	Berzofsky, et al., "Antigenic Peptides Recognized by T lymphocytes from AIDS Viral Envelope-Immune Humans", Nature, Vol. 334, pp. 706-708 (1988)

aminer

*Jeffrey Stucker*

Date Considered

*3/8/04*

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 809; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.



INFORMATION DISCLOSURE  
CITATION

(Use several sheets if necessary)

App. Docket No.

1579-548

Applicant

HAYNES et al

Filing Date

February 5, 2001

Serial No.

09/775,805

Group

1648

<i>JS</i>	Clerici, et al., "Detection of Cytotoxic T Lymphocytes Specific for Synthetic Peptides of gp160 in HIV-Seropositive Individuals", The Journal of Immunology, Vol. 146, No. 7, pp. 2214-2219 (1991)
	Hart, et al., "Priming of an Anti-Human Immunodeficiency Virus (HIV) CD8 <sup>+</sup> Cytotoxic T Cells <i>In Vivo</i> by Carrier-Free HIV Synthetic Peptides", Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 9448-9452 (1991)
	Haynes, et al., "Conversion of an Immunogenic Human Immunodeficiency Virus (HIV) Envelope Synthetic Peptide to a Tolerogen in Chimpanzees by the Fusogenic Domain of HIV gp41 Envelope Protein", The Journal of Experimental Medicine, Vol. 177, pp. 717-727 (1993)
	Haynes, et al., "Induction of HIVMN Neutralizing Antibodies in Primates Using a Prime-Boost Regimen of Hybrid Synthetic gp120 Envelope Peptides", The Journal of Immunology, Vol. 151, No. 3, pp. 1646-1653 (1993)
	Hosmalin, et al., "Priming with T Helper Cell Epitope Peptides Enhances the Antibody Response to the Envelope Glycoprotein of HIV-1 in Primates", The Journal of Immunology, Vol. 146, No. 5, pp. 1667-1673 (1991)
	Liao, et al., "Increased Immunogenicity of HIV Envelope Subunit Complexed with $\alpha_2$ -Macroglobulin When Combined with Monophosphoryl Lipid A and GM-CSF", Vaccine, Vol. 20, pp. 2396-2403 (2002)
	Shirai, et al., "Broad Recognition of Cytotoxic T Cell Epitopes from the HIV-1 Envelope Protein with Multiple Class I Histocompatibility Molecules", The Journal of Immunology, Vol. 148, No. 6, pp. 1657-1667 (1992)

aminer

Date Considered

3/8/04

Examiner: Initial if reference considered whether or not citation is in conformance with MPEP 808; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

### FORMATION DISCLOSURE CITATION

ATTY. DOCKET NO.

SERIAL NO.

1579-548

09/775,805

APPLICANT

HAYNES et al

(Use several sheets if necessary)

FILING DATE

GROUP

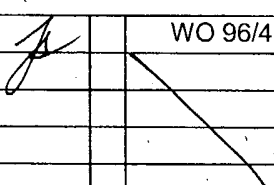
February 5, 2001

1648

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

							TRANSLATION	
DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	YES	NO		
 WO 96/41189	12/1996	WIPO	—	—				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

[illegible]

\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-FB-A820 (Also PTO-1449)

